UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,322	02/28/2002	Abbot F. Clark	1910	8526

7590 09/27/2006

Alcon, Inc.
c/o Alcon Research, Ltd.
Patrick M. Ryan(Q-148), R&D Councel
6201 So. Freeway
Fort Worth, TX 76134-2099

EXAMINER	
ZEMAN, ROBERT A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/085,322	CLARK, ABBOT F.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment and response filed on 7-10-2006 are acknowledged. Claims 1, 3-4 and 6-8 have been amended. Claims 2 and 5 have been canceled. Claims 1, 3-4 and 6-10 are pending and currently under examination.

Claim Rejections Withdrawn

The rejection of claims 1 and 4 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using aminoglycoside antibiotics to treat glaucoma caused by a premature stop mutations in a gene, does not reasonably provide enablement for using aminoglycoside antibiotics to treat any other ophthalmic disease caused by a premature stop mutations in a gene is withdrawn in light of the amendment thereto.

The rejection of claims 1-2, 4-5 and 7-8 under 35 U.S.C. 102(a) as being anticipated by Miller et al. (Journal of the American Animal Hospital Association, 2000, Vol. 36 No. 5, pages 431-438) in light of Alward et al. (New England Journal of Medicine, 1998, Vol. 338 No. 15, pages 1022-1027) is withdrawn in light of the amendment thereto.

The rejection of claims 1-10 under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (Journal of the American Animal Hospital Association, 2000, Vol. 36 No. 5, pages 431-438) and Barton-Davis et al. (Journal of Clinical Investigation, 1999, Vol. 104 No. 4, pages 375-381 – IDS filed 2-28-2002) in light of Alward et al. (New England Journal of Medicine, 1998, Vol. 338 No. 15, pages 1022-1027) is withdrawn in light of the amendment thereto.

New Grounds of Rejection

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubenstein et al. (Current Opinions in Pediatrics, 1998, Vol. 10, pages 250-255 – IDS filed 2-28-2002) and Alward et al. (New England Journal of Medicine, 1998, Vol. 338 No. 15, pages 1022-1027).

The instant claims are drawn to methods of treating an open-angle glaucoma caused by premature stop mutations in a gene (GLC1A or CYP1B1) by administering a composition comprising an aminoglycoside antibiotic compound (gentamicin) wherein said composition can be topically administered as an eye drop.

Rubenstein et al. disclose that low levels of aminoglycoside antibiotics are known to stimulate suppression and cause read-through of stop codons in both prokaryotes and eukaryotes (see page 251, left hand column). Rubenstein et al. further disclose that gentamicin could decrease the efficiency of premature translation at nonsense mutations (stop codons) in CFTR and promote the production of full-length CFTR mRNA (see page 251, left hand column).

Rubenstein et al. differs from the instant invention in that they do not explicitly disclose the use of aminoglycoside antibiotics generally, or gentamicin specifically for the treatment of

open-angle glaucoma that is caused by premature stop mutations in either the GLC1A or CYP1B1 genes. Rubenstein also differs from the instant invention in that they do not explicitly disclose the recited antibiotic concentrations recited in claims 9-10 or the direct application of the aminoglycoside antibiotic to the eye via eye drops.

Alward et al. disclose glaucoma is associated with stop mutations in the GLC1A gene (see abstract and Table 4 on page 1026).

It would have been *prima facie* obvious to use low levels of aminoglycoside antibiotics (gentamicin) as disclosed by Rubenstein et al. to treat open-angle glaucoma in order to take advantage of the reduced side effects associated with antibiotic treatments as opposed to other treatments for open-angle glaucoma (i.e. hormones etc.).

One would have had a reasonable expectation of success as Rubenstein et al. disclose that low levels of aminoglycoside antibiotics are known to stimulate suppression and cause read-through of stop codons in both prokaryotes and eukaryotes and Alward et al. disclose that open-angle glaucoma is associated with premature stop mutations in the GLC1A gene. With regard to the concentrations recited in claims 9-10 and the route of administration recited in claims 4 and 8, it is deemed that it would have been obvious for the skilled artisan to administer the aminoglycoside antibiotics directly to the eye via eye drops as this constitutes the standard means of delivering an ocular treatment compound. Additionally, it would have been obvious for the skilled artisan to optimize the concentration of the aminoglycoside antibiotic and it is deemed that this optimization would necessarily encompass the recited concentrations. Consequently, the recited references render all the limitations of the instant claims obvious.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ROBERT A. ZEMAN
PRIMARY EXAMINER

September 20, 2006